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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/790,417

03/01/2004

Charles A. Mesko

MESK / 30

1471

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EXAMINER

GEMBEH, SHIRLEY V

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

10/05/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/790,417

Applicant(s)

MESKO, CHARLES A.

Examiner

Shirley V. Gembah

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 January 1960.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 20-21, 23, 25-29, 31, 32, 34, 35, 37-42 and 45 is/are rejected.
- 7) ☒ Claim(s) 8-19, 22, 24 30, 33, 36, 43-44 and 46-60 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 6/11/04, 10/1/04 and 8/22/05 have been received and reviewed. However, under Other documents items C.R and A.R. A. R cited as a search report is not a non-patent literature and C.R does not have a valid publication date. They have been placed in the file.

Claim Objections

Claims 8-19, 22, 24 30, 33, 36, 43-44 and 46-60 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Art Unit: 1614

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims **1-7, 20-21, 27-28, 37-42 and 45** are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **40-45** of U.S. Patent Application No. **10374594**. Although the conflicting claims are not identical, they are not patentably distinct from each other. The reasons are as follows:

Both sets of claims refer to a pharmaceutical acceptable composition – a genus – homeopathic agent in the co-pending application (claims 40-45) and a specie from hormone agents (claims **11-7, 20-21, 27-28, 37-42 and 45**) in the copending application. The current application claims anticipate the copending application claims

Both applications recite using the same compositions/or derivatives thereof. See current application claims 40-45 and copending application claims **1-7, 20-21, 27-28, 37-42 and 45**. The compositions recited in the claims are anticipatory of each other.

In view of the foregoing, the copending application claims and the current application claims are obvious variations.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 23, 29 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Garfield et al., US 5,595,970.

Garfield et al., teach a pharmaceutical composition comprising a hormone (progestin) and a nitric oxide as required by instant claim 1 and 31, see col. 4, lines 50-54. Nitric oxide activates guanylate cyclase to increase the cellular content of cGMP. See col.1, line 67 bridging col. 2, lines 1-3. The reference also teaches the composition is in the form of capsule, see col. 6, lines 20-22 as required by instant claim 23 wherein the composition comprises plurality of inactive ingredients such as water, flavoring etc., which do not react with the active agents, see col. 6, lines 1-13 as required by instant claim 29.

Claims 1-3, 23, 29 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Chwalisz et al., US 5,906,987.

Chwalisz et al., teach a pharmaceutical composition comprising a hormone (testosterone ester/testosterone) and a nitric oxide as required by instant claims 1-2 and 31 see col. 4, lines 20-32. Nitric oxide is an effector on cGMP. See col.2, lines 23-25. The reference also teaches the composition is in the form of capsule, see col. 7, lines 59-60 as required by instant claim 23, wherein the composition comprises plurality of inactive ingredients such as water, flavoring etc., which do not react with the active agents, see col. 7, lines 27-40 as in instant claim 29. With regard to instant claim 3, it is anticipated that the testosterone will potentiate lutenizing hormone.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1614

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 6, 20, 21, 23, 25, 26, 29, 31-32, 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garfield et al., US 5,595,970 taken with Chwalisz et al., US 5,906,987 and Coral-Cure www.coral-cure.com/mens-health in view of Chen et al. Exp. Opin. Ther. Patents.

Garfield et al and Chwalisz are applied here as supra. Further Garfield et al teach inhibition of nitric oxide synthase dramatically increases blood pressure, thus teaches the limitations of claims 34-35, see col. 2, lines 19-22.

Coral-cure teaches a homeopathic form 10X topical formulation comprising testosterone the hormone, chrysin, estrogen blocker, Tribulus L. Terrestris the lutenizing hormone as in claims 1-3, 6, 20-21, 31-32.

With regards to the phosphatidyl choline the vesicle carrier chen and al. teach the use of phosphatidyl choline in topical application as in current claims 25-26.

One of ordinary skill in the art would have combined the references recited above and included a phosphatidyl choline as the visicle carrier in claims 25-26 because the particles are liposomes and have means for binding to microorganisms present on the skin, for example those responsible for skin disorders and elevate blood plasma.

Art Unit: 1614

Therefore one of ordinary skill in the art would have been motivated to include a phosphotidyl choline because it is a major component of cellular membranes and functions in the transport of lipoproteins in tissues.

One of ordinary skill in the art would have used the homeopathic cream by coral-cure because it contains a testosterone in a cream, thus a vesicle operable for transporting the testosterone from the external body site to an internal second body site and stimulate blood flow to the organs needed. In the instant application the cream is rubbed on the penis wherein the steroid/hormone-testosterone stimulates are known to regulate nitric oxide synthesis and nitric oxide effector system cGMP. One of ordinary skill in the art would have been motivated to include in the pharmaceutical composition a Tribulus L. Terrestris because in some cultures, the tribulus terrestris plant has been used as a "tonic" to increase energy levels and treat sexual dysfunction (usually in males) as evident by <http://www.ironmagazine>.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed

invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Thus, the claimed invention was *prima facie* obvious to make and use at the time it was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/790,417

Page 8

Art Unit: 1614

SVG

9/27/07

Ardin H. Marschel 9/30/07

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER